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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/634,581

08/05/2003

Robert Johnson

PC027355

1446

26648 7590 07/31/2008
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EXAMINER

KIM, YUNSOO

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

07/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/634,581	Applicant(s) JOHNSON ET AL.	
	Examiner YUNSOO KIM	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-12 and 29-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-12,29-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3-5, 7-12 and 29-36 are pending.
2. The following rejection remains.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-5, 7-12 and 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Athwal et al. (WO01/94585, IDS reference, No.1, of record) in view of Relton (WO97/45140, of record) as is evidenced by the U.S. Pat. No. 6,171,586 (of record), IDS reference, for the reasons set forth in the office action mailed 1/24/08.

Applicants' arguments filed on 4/24/08 have been fully considered but they are not persuasive.

Applicants argue that it is not prima facie obvious to combine the teachings of the '585 publication into the '140 publication because the combination of the references does not suggest of teach the antibody formulation being stable at 25°C for at least twelve weeks and no stability data is provided in the '140 publication.

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Applicants further argued that it is incorrect to assert the claimed formulation and the referenced formulation taught by the '140 publication are identical because the NaCl or polysorbate is not required in the claimed invention.

As it was stated in the previous office action, the claimed stabilizing formulation requires a buffer maintaining pH of 3.5-6 (acetate), tonifying amount of salt (NaCl) as in claims 1, 10, 12 and 29 and this limitation is taught in the Example 4 of the '140 publication. The referenced buffer formulation taught by the '140 publication is suitable for stabilizing antibody formulation of Fab fragments, bispecific antibodies (p. 4, line 26, in particular) or modified antibodies as is evidenced in the '586 patent. Therefore, the formulation taught by the '140 publication in stabilizing antibody and the claimed buffer formulation are identical.

Moreover, the claimed formulation is not limited to an antibody formulation consisting of a modified antibody and a buffer which excludes addition of other components. However, the claimed stable antibody formulation recites "comprising" and it allows addition of polysorbate, or tonifying amount of salt.

The modified antibody CDP870 was taught by the '585 publication and the obviousness rejection was based on the combination of references. One cannot show unobviousness by attacking references individually where the rejection was based on the combination of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, the antibody formulation being stable 25°C for at least twelve weeks is an expected property of the buffer formulation containing the antibody.

Therefore, the combination of reference teachings remains obvious.

5. No claim is allowable.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7 Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim


Patent Examiner

Technology Center 1600

July 22, 2008

/ILIA OUSPENSKI, Ph.D./

Primary Examiner, Art Unit 1644

<i>Application Number</i> 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/634,581	JOHNSON ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	